

Fetal Monitoring Technology Application Note

This application note explains how Philips fetal monitoring technology supports safe and accurate fetal and maternal monitoring. Four technological aspects are collected together here:

- Precision Signal Track and Hold
- Cross-Channel Verification
- Fetal Heart Rate Baseline Offset
- Fetal Movement Profile

Precision Signal Track and Hold

This technology allows the monitor to track the fetal heart rate signal very closely to ensure an accurate fetal heart rate measurement with almost no gaps.

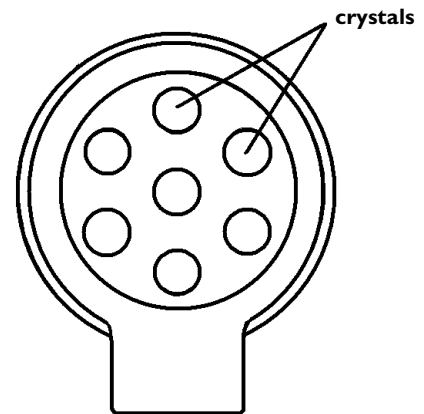
The signal is monitored with two ultrasound receiver channels so that two overlapping time windows can be monitored (ultrasound travelling time=depth). When the signal is strong in both windows the optimal monitoring depth is found. The measurement window stays in this position while the control window is moved in both directions to check the strength of the signal at different depths. When the control window registers a change in the signal position (due to movement of the fetus or mother) the measurement window is moved to the new optimal position. This adaptation to changing depth happens with each heart beat and so virtually eliminates gaps in the trace due to lost signals.

As the signal is so well tracked, the measurement window around the heart can be made as small as

possible thus reducing the ultrasound energy that mother and fetus are exposed to.

Ultrasound Crystal Placement for Optimal Geometry

The crystals in the Ultrasound transducer are located six around the circumference and one in the center. In this configuration, all lines between crystals are equidistant. If a line were drawn from crystal to crystal, a series of equilateral triangles would be created. This allows the coverage area to be homogenous, or of equal signal strength throughout.

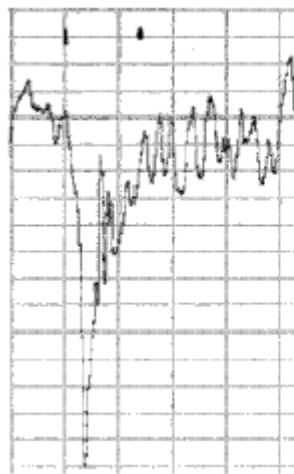


A homogenous signal eliminates any "dark spots" in the beam, which will reduce the number of times the clinician will need to reposition the transducer. If there are more than 7 crystals within a transducer there are no longer equidistant lines between the crystals and the triangles created are isosceles triangles. This configuration is unlikely to provide a homogenous signal, but rather "dark spots" within the beam.

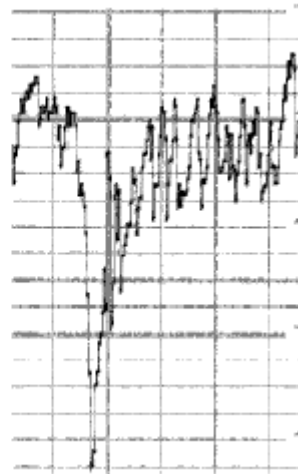
Correlation to Directly Measured FHR

The signal tracking and the homogenous ultrasound signal from the 7-crystal transducer both contribute to a fetal heart rate measured by ultrasound which correlates very highly to the directly measured fetal

heart rate. The degree of smoothing caused by autocorrelation signal processing is reduced to a minimum as seen in the following comparison of traces.



fetal trace from ultrasound



original DECG trace

Cross-Channel Verification

Cross-Channel Verification indicates when the same heart rate is being recorded by different transducers.

When the maternal heart rate and fetal heart rate are being monitored, Cross-Channel Verification will alert you when the values are the same. This may be an indication that the fetus is deceased and the transducer is picking up a signal from the maternal heart or a large blood vessel.

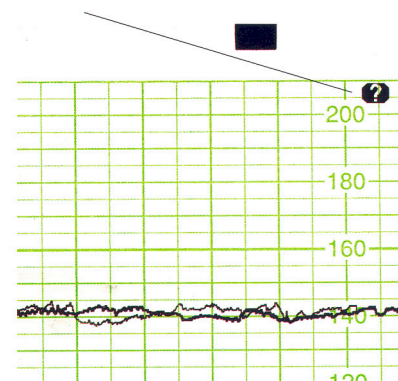
Cross-Channel Verification can compare all fetal and maternal heart rates and indicates when multiple channels are picking up the same signal. This means when monitoring multiples and maternal heart rate simultaneously Cross-Channel Verification will compare the values from all fetuses and each of these values with the maternal heart rate.

This technology helps reduce potential legal liability associated with continuing to monitor an incorrect heart rate.

When signal “cross-over” occurs, you are alerted within approximately 60 seconds to check the traces and potentially reposition the transducers.

Note: Be aware that a maternal heart rate trace can exhibit features that are very similar to those of a fetal heart rate trace, even including accelerations and decelerations. Do not rely solely on trace pattern features to identify a fetal source.

Figure 1 CCV symbol prints on the trace when two channels are recording the same heart beat

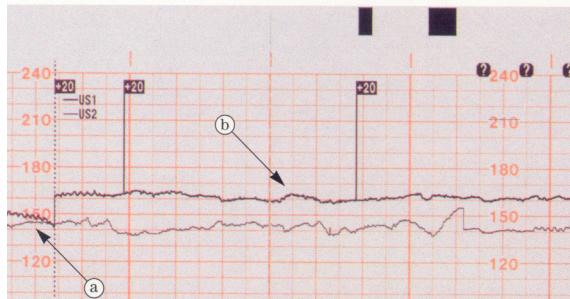


Cross-Channel Verification Plus (CCV+) indicator (Series 50 XMO, not available in the USA and Japan)

To warn you if you accidentally record maternal SpO₂ instead of fetal SpO₂, (because the sensor is facing the uterine wall instead of the fetus) the monitor compares the heartrate it derives from DECG on the Cardio 1/Combi channel, (or from US on the Cardio 2 channel if DECG is not in use) with the pulse rate it derives from FSpO₂. The CCV+ indicator illuminates and **?** is printed on the trace if the monitor records a pulse rate from FSpO₂ and a heart rate from DECG or ultrasound that do not match for more than one minute.

FHR Baseline Offset

When the baselines of multiple FHR traces are very similar, independent trend interpretation can be difficult. To alleviate this, you can offset a baseline by 20 bpm. You can deactivate the offset feature and return the FHR trace to its original baseline anytime you wish.



A section of a twins' tracing is shown above. It shows the FHR 1 trace before (Line a) and after (Line b) the baseline offset feature is activated. To indicate the recording is in the offset mode, a +20 symbol is repetitively printed at the top of the trace.

Fetal Movement Profile

Study finds Philips' FMP saves clinicians' and patients' time, costs, and undue concern

Fetal movement is recognized as an important indication of fetal condition. Consequently, recordings of fetal movement are increasingly being obtained as part of routine antepartum screenings in obstetricians' offices, clinics and hospitals.

In use in Europe, the United States and Japan since 1991, Philips Fetal Monitors simultaneously assess fetal heart rate (FHR), fetal gross body movement via the Fetal Movement Profile (FMP) parameter, and uterine activity.

Benefits of the FHR-FMP assessment range from:

- helping clinicians determine the baseline heart rate - especially in difficult-to-interpret traces, to
- predicting and supervising high risk pregnancies which involve a number of fetal disorders, including fetal growth retardation (IUGR).

One of the most important benefits of Philips' FMP monitoring is its efficiency and cost effectiveness as an early screening tool.

Clinical trials confirm that the use of Philips Fetal Monitors in routine antepartum screenings reduces the number of patients with "suspicious" FHR test results, thus eliminating their need for additional expensive, second-level testing at the hospital. For the patient, this represents significant savings in time, cost and concern. It also means cost savings for the health care system.

Fetal Movement and Fetal Heart Rate

The classic evaluation of fetal movement employs the mother's own perception. Clinical trials show that the Philips Fetal Monitors detect on average 40 percent more movement than perceived by the mother. Not only can they assure both mother and clinicians of a more accurate level of fetal movement detection, but the FMP, recorded simultaneously with the heart rate, helps in the interpretation of the FHR trace.

Physicians know that heart rate is directly influenced by the physical activity of the fetus and they can assign the baseline heart rate more efficiently with the Fetal Movement Profile recording.

Furthermore, studies confirm that reduced or lack of fetal gross body movement often precedes the change in FHR pattern associated with intrauterine growth retardation (IUGR)

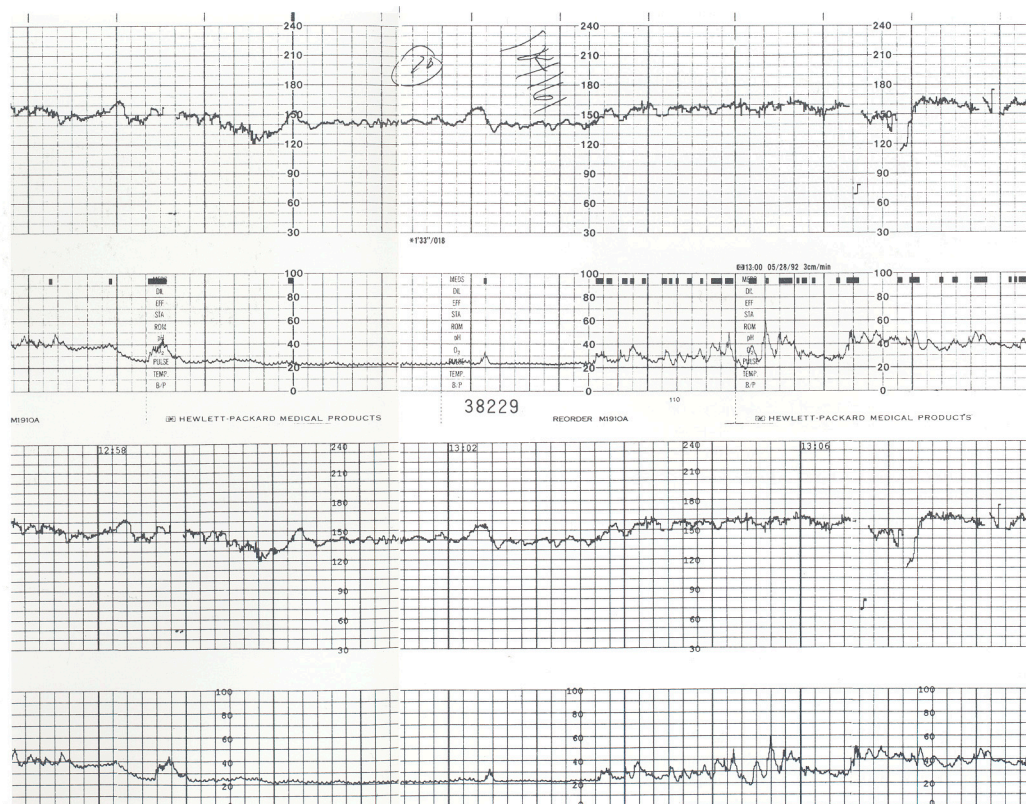


Figure 2 The FMP information provided by the Philips Fetal Monitors enhances the clinician's ability to assign the baseline FHR. Specifically as shown here (lower trace), without the assistance of FMP, the baseline FHR is unclear. With the fetal movement data (upper trace), the baseline FHR and accelerations are clearly recognizable.

More Efficient Antepartum Screening

Used as a non-invasive tool in nonstress testing, Philips' FHR-FMP monitoring employs two of the five parameters of the Fetal Biophysical Profile (BPP). This is a second-level testing prescribed for high-risk pregnancies. These two parameters, along with the measurement of uterine activity, provide a more efficient way to assess fetal condition. Clinical trials have shown a 50 percent reduction in the number of reported "suspicious" nonstress test (NST) results.

In a one-year clinical trial conducted at the Women's Hospital, University of Southern California School of Medicine, 3,500 women received antepartum screening using Philips Series 50 Fetal Monitors.

Normally, 5 to 6 percent of women who undergo the nonstress FHR test (NST) at Women's Hospital present "non-reactive" results; that is, the fetus fails to show qualifying accelerations of heart rate. (Test

periods are 40 minutes. In 40 to 60 percent of the tests, acoustic stimulators are used.)

In the 3,500 tests using monitors with FMP, the "non-reactive" percentage dropped to 3 percent. After the clinical trials were concluded and the equipment removed, the reported rate of "suspicious" nonstress test returned to the higher level.

"The fetal Movement Profile is a tool that makes our testing approach and interpretation better", states Dr. Richard H. Paul, Professor of Gynecology at the University of Southern California School of Medicine, and Chief of Maternal Fetal Medicine at the Women's Hospital. "It has proven to be a great addition to our antenatal program. Second level evaluation procedures are expensive and time-consuming for patients and the hospital alike. With the FMP monitors, we reduced the number of these advanced evaluations in half!"

Early Detection and Supervision of High-Risk Pregnancies

Traditionally clinicians have waited until the mother complains of reduced fetal movement before initiating further testing such as ultrasound imaging. However, with routine screening using the Philips fetal monitors with FMP, fetal movement levels can be automatically, accurately, and reliably identified. Patients with FHR-FMP traces indicating little or no fetal movement can then be referred for fetal BPP testing, which also assesses fetal tone, fetal breathing and amniotic fluid volume. This can assist in identifying potential abnormalities.

With the FHR-FMP test, clinicians can screen patients for conditions associated with reduced movement, one of which is intra-uterine growth retardation (IUGR). Studies show that as many as 50 percent of pregnancies with fetuses below the 10th percentile in weight (considered growth retarded) go undetected by normal clinical examination.

Once IUGR is suspected, supervision of the pregnancy is intensified. FMP fetal monitors can play an important role in establishing movement trends during the important growth weeks of gestation. (IUGR may be associated with hypertension, antepartum hemorrhage, diabetes, heavy smoking, chromosomal anomalies and many other factors.)

At University Women's clinic in Homburg/Saar, Germany, Drs W Schmidt and J Gnirs validated the accuracy of Philips' FMP parameter. Using a Series 50 fetal monitor, they tracked the test results of 217 patients with normal or pathologic (below the 25th percentile in fetal weight) pregnancies between 28 and 42 weeks gestation. Comparing them with the results of independently taken sonographic studies, they found a 90 percent correlation.

Presented on the following pages are the traces of one of their patients between gestation weeks 30 and 33. The traces show a steady reduction of movement, leading to a diagnosis of IUGR. Sonographical biometry verified the slowing of fetal growth, showing the fetus' size falling below the normal range for its gestation age, beginning in week 22. The baby was delivered by cesarean and required intensive care.

IUGR Case Study

The following is a case study of a patient monitored by a Series 50 Fetal Monitor with FMP. Fetal movement "blocks" and "block clusters" are automatically recorded on the traces (see highlighted areas). In weeks 30 to 33, each successive FHR trace shows a reduction of fetal movement. This fetus was diagnosed as IUGR. The sonographical biometry chart verifies the slowing of fetal growth and how the size of this fetus falls below the normal range for its gestational age beginning in the 22nd week.

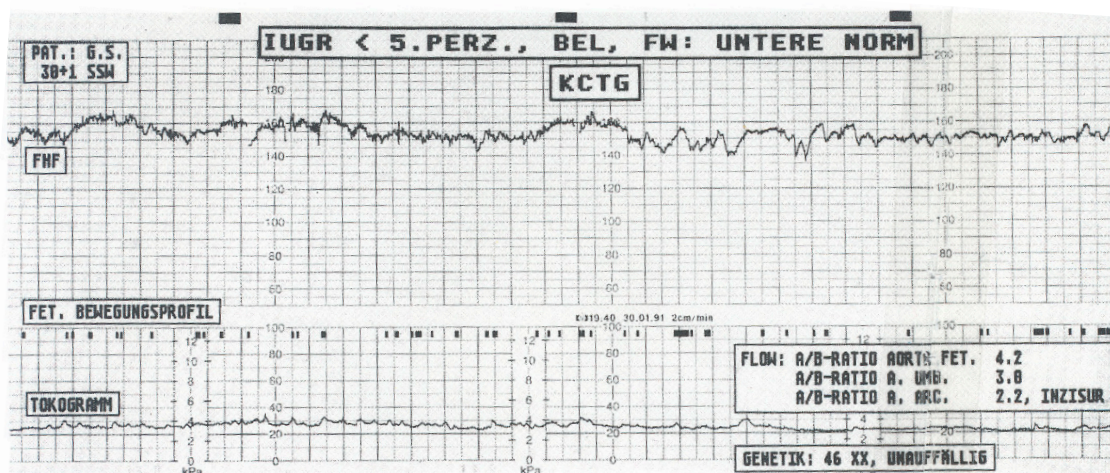
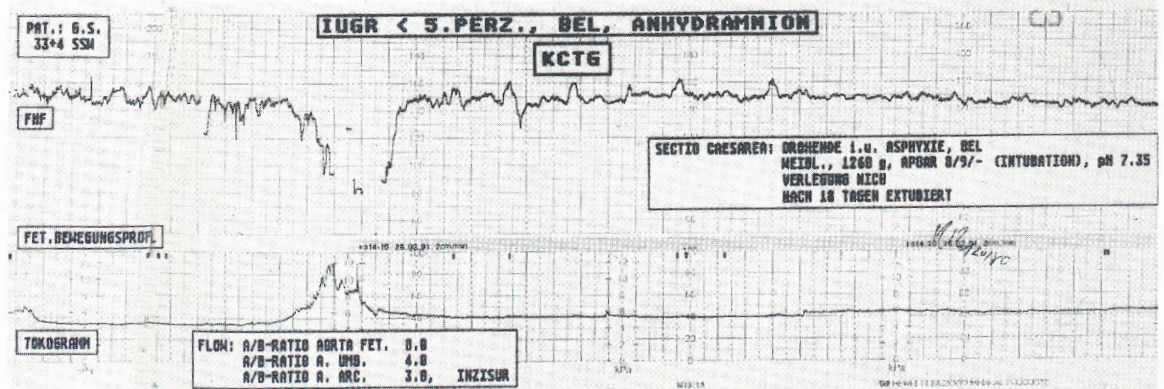
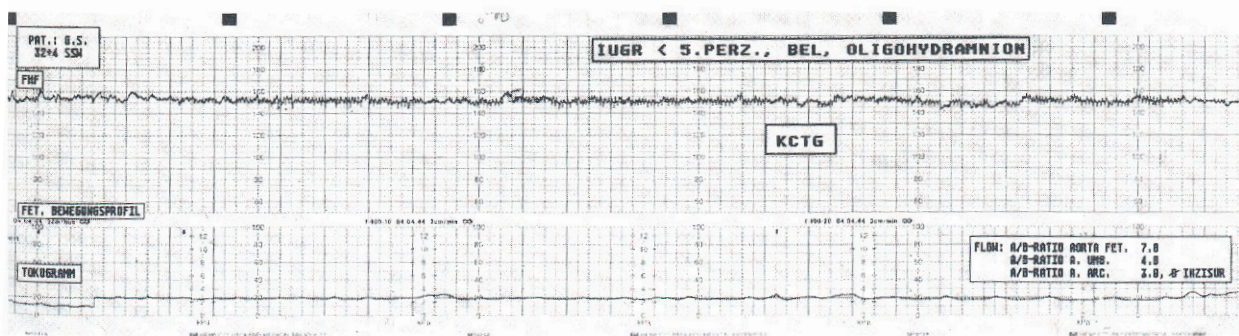
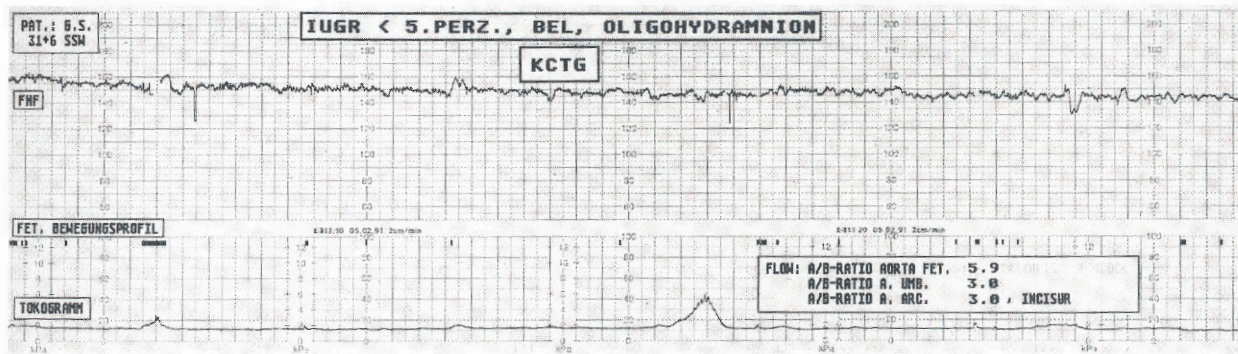


Figure 3 Special thanks to Prof.Dr. W Schmidt and Dr. J. Gnirs of the University Hospital, Department of OB/GYN, Homburg/Saar, Germany for sharing these original traces with us.



Key to German FHR-FMP Traces

OLIGOHYDRAMNION = Oligohydramnios

SECTIO CESAREA = Cesarean Section

SSW = Week of Gestation

TOKOGRAMM = Uterine Activity

UNAUFAELLIG = Normal or Inconspicuous

UNTERE NORM = Lower than the Normal Value

VERLEGUNG NICU = Transfer to NICU

WEIBL. = Female

5.PERZ = 5. PERC

A.ARC (Arteria Arcuata) = Arcuate Artery

ANYDRAMNION = Anydramnios

AORTA Fet. = Fetal Aorta

A.UMB. (Arteria Umbilicalis) = Umbilical Artery

BEL = Breech Presentation

DROHENDE i.u. ASPHYXIE = Fetal Compromise

FET. BEWEGUNGSPROFIL = Fetal Movement Profile

FHF = FHR

FLOW = Doppler Flow Velocity Analysis

FW = Amniotic Fluid Volume

GENETIK = Genetic Diagnosis

INZISUR = Endiastolic Notch

KCTG = FHR with Fetal Movement Profile parameter

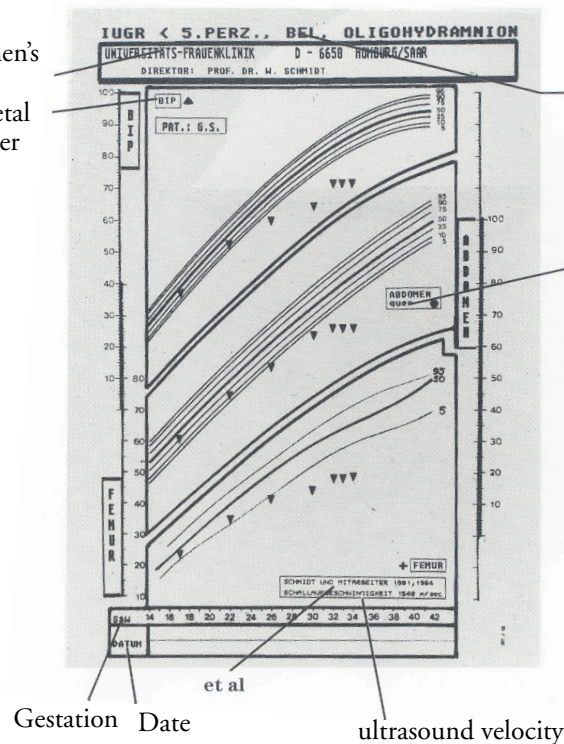
NACH 18 TAGEN EXTUBIERT = Extubation after 18 days

University Women's Hospital

Bi-parietal Diameter

Breech presentation

transverse abdominal diameter



Summary

The fetal Movement Profile, a parameter provided by Philips in fetal monitors, has been accepted as an important additional tool for assessing fetal wellbeing.

Together with the other features described in this Application Note: Precision Signal Track and Hold, Cross-Channel Verification and Baseline Offset, FMP represents a significant contribution to safety and accuracy in fetal and maternal monitoring.

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www.medical.philips.com

Via e-mail

Our e-mail for all remarks and requests is:

medical@philips.com

By fax

We can be reached at the following fax number:

+31 40 27 64 887

By postal service

Please write to us at the following address:

Philips Medical Systems

Global Information Center

I.B.R.S. / C.C.R.I. Numéro 11088

5600 VC Eindhoven

Pays-Bas / The Netherlands

(no stamp required)

United States:

Philips Medical Systems
Cardiac and Monitoring Systems
3000 Minuteman Road
Andover, MA 01810
(800) 934-7372

Canada:

Philips Medical Systems Canada
281 Hillmount Road
Markham, ON
L6C 2S3
(800) 291-6743

Europe, Middle East and Africa:

Philips Medizin Systeme Böblingen GmbH
Cardiac and Monitoring Systems
Hewlett-Packard Str. 2
71034 Böblingen
Germany
Fax: (+49) 7031 463 1552

Latin America Headquarters:

Philips Medical Systems
1550 Sawgrass Corporate Parkway #300
Sunrise, FL 33323
Tel: (954) 835-2600
Fax: (954) 835-2626

Asia Pacific Headquarters:

Philips Medical Systems
30/F Hopewell Centre
17 Kennedy Road
Wanchai
Hong Kong
Tel: (852) 2821 5888
Fax: (852) 2527 6727

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